

REMARKS

The Office Action sent June 20, 2008 has been received and reviewed. All claims currently under consideration stand objected to or rejected. Applicant notes with appreciation the partial withdrawal of the previous objections and rejections. All amendments are made without prejudice or disclaimer.

Support for the current amendments can be found throughout the Specification, for example, in at least paragraphs [0015], [0057], [0064], [0075], [0082], [0086], [0102], and [0104]-[0106] of the Specification as published and the claims as previously presented. Accordingly, applicant submits that no new matter has been added. Reconsideration is respectfully requested.

Claims 28 and 29

Claims 28 and 29 stand withdrawn. Applicant respectfully requests clarification with regard to the withdrawal of claims 28 and 29. In the most recent restriction requirement and the response thereto, applicants elected Group VIII drawn to an isolated or recombinant nucleic acid molecule comprising SEQ ID NO:37. As claims 28 and 29 are drawn to a nucleic acid molecule comprising SEQ ID NO:37, claims 28 and 29 should not be withdrawn. Applicant respectfully requests consideration of claims 28 and 29.

35 U.S.C. § 112

Claims 21-27 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. Specifically, the Office alleges that the Specification does not describe or include any nucleic acids that both hybridize to SEQ ID NO: 37 in accordance with claimed conditions, and complement a nucleotide sequence that encodes a fibronectin/fibrinogen binding protein of *Streptococcus suis*. Office Action, page 4. Applicant respectfully traverses the rejection.

Applicant refers to the working examples in the Specification that illustrate a nucleotide sequence that hybridizes with nucleotides 89-263 of SEQ ID NO:37 and remains hybridized under the claimed conditions, in addition to, the nucleotide sequence's complement encoding a fibronectin/fibrinogen binding protein of *Streptococcus suis*. For example, paragraphs [0105]-

[0106] describe the production and/or isolation of a 5kb fragment and pFBPS7-46, both of *Streptococcus suis* origin. Specifically, paragraph [0105] states that SEQ ID NO:37 was used as a probe to identify a chromosomal fragment of *S. suis* serotype 2 containing flanking *fbps* sequences. See Paragraph [0105]. Because the chromosomal fragment was identified using the SEQ ID NO:37 probe, this fragment must inherently include a complementary sequence to that of SEQ ID NO:37. This fragment, a 5 kb EcoR1 fragment, was subsequently identified and cloned, yielding pFBPS7-46. *Id.* The Specification illustrates pFBPS7-46 in FIG. 1 and references in [0102] a deposit in Genbank under accession no. AF438158. Accordingly, the Specification describes the isolation of a nucleotide sequence included as part a 5 kb EcoR1 fragment and pFBPS7-46 , and presents structure and sequence data in accordance with instant claims.

Additionally, the evidence of record shows that the resulting pFBPS7-46 and 5kb fragment therein, necessarily include the nucleotide sequence 89-263 of SEQ ID NO:37. A sequence analysis revealed that pFBPS7-46 and the 5kb fragment contained the entire *fbps* gene of *S. suis* serotype 2. Paragraph [0105]. An alignment (using BLAST) of the *fbps* gene submitted to Genbank with nucleotides 89-263 of SEQ ID NO:37 reveals that the *fbps* gene disclosed in the Specification includes nucleotides 89-263 of SEQ ID NO:37. [Alignment shown on following page]. Because the disclosed pFBPS7-46 and 5kb fragment include the *fbps* gene, the disclosed pFBPS7-46 and 5kb fragment necessarily include nucleotides 89-263 of SEQ ID NO:37.

The Specification further demonstrates that the disclosed pFBPS7-46 and 5kb fragment necessarily include a nucleotide sequence that hybridizes with nucleotide sequences 89-263 of SEQ ID NO:37. The Specification states that the 5kb fragment, including SEQ ID NO:37, was cloned into pFBPS7-46. Paragraph [0105]. The *fbps* gene in pFBPS7-46 was subsequently amplified using PCR and further cloned into expression constructs. Paragraph [0086]. The amplification processes and the expression constructs are, by definition double stranded. Because the expression constructs and amplification processes were necessarily double stranded and necessarily included SEQ ID NO:37, the full complementary nucleotide sequence that fully hybridizes to SEQ ID NO:37 must be present as well. Accordingly, applicant respectfully submits that an isolated or recombinant nucleic acid molecule comprising a contiguous sequence

which hybridizes to the full length of nucleotides 89-263 of the nucleotide sequence of SEQ ID NO:37 is fully described by the Specification.

Alignment of *fbps* and nucleotides 89-263 of SEQ ID NO:37

gb|AF438158.1| Streptococcus suis fibronectin/fibrinogen binding protein
(fbps)
gene, complete cds; and alpha-acetolactate decarboxylase
gene, partial cds
Length=2179

Score = 320 bits (173), Expect = 2e-91
Identities = 174/175 (99%), Gaps = 0/175 (0%)
Strand=Plus/Plus

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Query    89      CTCCTGACCACCTATNTGCATCAAGTGCCAAATGACCAGTCGAGTGTGCGGTTAGACAAC  148
          |||
Sbjct    1198     CTCCTGACCACCTATGTGCATCAAGTGCCAAATGACCAGTCGAGTGTGCGGTTAGACAAC
1257

Query    149      TACTATACGGGCAAGGAAGTGGAGATTGAGTTGGATGTGGCTTTGACTCCTAGCCAAAAT  208
          |||
Sbjct    1258     TACTATACGGGCAAGGAAGTGGAGATTGAGTTGGATGTGGCTTTGACTCCTAGCCAAAAT
1317

Query    209      GCCCAGCGGTACTTCAAGAAGTACCAGAACTCAAGGAGGCGGTCAAGCACCTGA  263
          |||
Sbjct    1318     GCCCAGCGGTACTTCAAGAAGTACCAGAACTCAAGGAGGCGGTCAAGCACCTGA  13721

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Furthermore, applicant respectfully submits that the Specification more than adequately discloses that the complement of the disclosed nucleotide sequence encodes for a portion of a fibronectin/fibrinogen binding protein of *S. suis*. As illustrated in the previous paragraphs, the disclosed contiguous nucleotide sequence in pFBPS7-46 and the 5kb fragment hybridizes to nucleotides 89-263 of SEQ ID NO:37. Thus, SEQ ID NO:37 is a complement of the claimed nucleotide sequence. The evidence of record clearly illustrates that nucleotides 89-263 of SEQ ID NO:37 encode for at least a portion of a fibronectin/fibrinogen binding protein of *S. suis*. See, e.g. remarks in previous paragraphs, paragraphs [0102], [0105], etc. Thus, the Specification

¹ Applicant notes that the single gap in the alignment is where SEQ ID NO:37 recites "N" at position 104. SEQ ID NO:37, at page 38 of the Specification as published, recites that the N is a, c, g, or t. Thus, if N = G, as provided for in the description of SEQ ID NO:37, then SEQ ID NO:37 and a portion of *fbps* are identical.

discloses a complement (e.g. SEQ ID NO:37) of the claimed nucleotide sequence that encodes for a portion of a fibronectin/fibrinogen binding protein of *S. suis*.

The Office alleges that the Specification does not provide a recognized correlation between structure and function. *See*, Office Action, page 5. The Office additionally alleges that the scope of the claims includes numerous structural variants and the genus is highly variant because a significant number of differences between genus members are permitted. *Id.* Further, the Office alleges that the Specification fails to provide guidance on the structure of the nucleic acid molecules. *See*, Office Action, page 5.

Applicant respectfully disagrees and notes that the Specification provides evidence that one of ordinary skill the art would conclude that the applicant was in possession of the instantly claimed nucleic acids. The previous remarks and evidence of record indicate that the Specification provides structure and sequence information of the claimed isolated nucleic acid (i.e., FIG. 1, Accession no. AF438158, etc.). The Specification further illustrates the isolated nucleic acid functions and is directed to fibrinogen/fibronectin binding.

The Specification further describes the structure and function of the *fbps* gene, stating that pFBPS7-46 and the 5kb contained an open reading frame of 1659 bp coding for a polypeptide of 553 amino acids. The *fbps* gene further included an ATG start codon, putative ribosomal binding sites upstream from the start codon, and putative promoter sequences. Further, the corresponding *fbps* amino acid sequence aligned with and was substantially homologous to fibronectin/fibrinogen-binding protein from other bacteria. Additionally, one of ordinary skill in the art would recognize the Specification's disclosure of such structure and function; as such disclosure is based on well-understood principles such as nucleic acid hybridization, sequence complementarity, and so forth.

Applicant additionally submits that the instantly claimed stringent hybridization conditions would enable a limited number of nucleic acid sequences to hybridize to SEQ ID NO:37. The variability would be further limited as a SEQ ID NO:37 probe illustrated that the *fbps* gene is similar and present in all known serotypes of *S. suis* (except for 32 and 34), as well as in all three phenotypes of serotype 2. *See, e.g.*, paragraphs [0022], [0112], and [0113]. Such a limited variability would be readily recognized by one of ordinary skill, as the basis for limited variability are clearly described by the Specification.

Applicant asserts that the present claims are more than adequately described, and therefore, respectfully requests withdrawal of the written description rejection under 35 U.S.C. § 112, first paragraph.

Claims 21-27 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the enablement requirement. Specifically, the Office alleges that the Specification fails to teach 1) hybridization occurring at 65°C in a buffer in accordance with present claims and 2) the identity of a nucleotide sequence which hybridizes to the full length of nucleotides 89-263 of SEQ ID NO:37, wherein the complement of the sequence encodes for a fibrinogen/fibronectin binding protein of *S. suis*. See, Office Action, pages 6-7. The Office further alleges that the present claims are not enabled, as any experimentation would require ingenuity beyond that expected of one ordinary skill in the art. *Id.* Applicant respectfully traverses the rejection.

Applicant references the working examples previously discussed, and respectfully asserts that the Specification more than adequately enables the present claims. First, the claimed hybridization and experimental conditions are expressly described in a working example of Paragraph [0082]. The Specification additionally provides a working example, wherein the nucleotide sequence of SEQ ID NO:37 was used as a probe, through hybridization, to identify a chromosomal DNA fragment of *S. suis* serotype 2 containing flanking *fbps* sequences. Further, the identity of the nucleotide sequence pFBPS7-46 (depicted in FIG. 1) was cloned and isolated.

As discussed in the paragraphs responding to the “written description” issues, the isolation, recombination, production, and/or cloning of pFBPS7-46 and the 5kb fragment, at the very least, inherently include the isolation recombination of a nucleotide sequence that hybridizes fully to sequences 89-263 of SEQ ID NO:37.

In the event that the Specification did not identify a nucleotide sequence, which is clearly not the case, the disclosure of SEQ ID NO:37 would be sufficient for enablement. Applicant respectfully notes and reiterates remarks submitted in the previous response of April 2, 2008. Determining a complementary or hybridizing sequence to the disclosed SEQ ID NO:37 would be no more than routine experimentation, as the basic A-T, C-G, or A-U hybridization principles would govern any potential hybridization of nucleotide sequences. Any potential variant nucleotide sequences would be further limited by the stringent hybridization conditions, as

previously discussed.

The Specification additionally demonstrates that the identified nucleotide sequence pFBPS7-46 encodes for a protein that is a fibrinogen/fibronectin binding protein. *See, e.g.* Paragraph [0106]. Indeed, experimental evidence in the Specification showed that the protein encoded by pFBPS7-46 was able to bind fibronectin and fibrinogen. *See* Paragraph [0107].

In light of the above, applicant asserts that the Specification provides more than adequate enablement for the present claims, and thus, respectfully requests withdrawal of the enablement rejection under 35 U.S.C. § 112, first paragraph.

Claims 21-27 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly including new matter. Applicants respectfully traverse the rejection.

As can be noted from the previous paragraphs, the Specification, in at least paragraph [0082], expressly describes the hybridization conditions as presently claimed.

Additionally, the Specification provides more than adequate disclosure for an isolated or recombinant nucleotide sequence that hybridizes to full length of nucleotides 89-263 SEQ ID NO:37. Applicant respectfully asserts that, at the very least, the Specification inherently discloses “a nucleotide sequence comprising a contiguous sequence which hybridizes to the full length of nucleotides 89-263 of SEQ ID NO:37.

Applicant respectfully notes that “[an] application may later be amended to recite the function, theory or advantage without introducing prohibited new matter. *See*, MPEP § 2163.07 (a), citing *In re Reynolds*, 443 F.2d 384, 170 USPQ 94 (CCPA 1971); *In re Smythe*, 480 F. 2d 1376, 178 USPQ 279 (CCPA 1973). The MPEP further states that “[b]y disclosing in a patent application a device that inherently performs a function or has a property, operates according to a theory or has an advantage, a patent application necessarily discloses that function, theory or advantage, even though it says nothing explicit concerning it.” *Id.* As is clear from the remarks presented herein, the inherent properties of the claimed nucleotide fragment (hybridizing to 89-263 of SEQ ID NO:37) are “necessarily present” in the disclosed pFBPS7-46 and 5kb fragment, and not a mere possibility.

As discussed in paragraphs responding to the “written description” issues, the Specification, at the very least, inherently describes an isolated or recombinant nucleotide

sequence that hybridizes to full length of nucleotides 89-263 SEQ ID NO:37. Applicant reasserts that the evidence of record demonstrates that pFBPS7-46 and the 5kb fragment necessarily include a recombinant or isolated nucleotide sequence that hybridizes fully to sequences 89-263 of SEQ ID NO:37 and that such an inclusion is not a mere possibility.

Additionally, as previously discussed, the Specification more than adequately discloses that the complement of the disclosed nucleotide sequence encodes for a portion of a fibronectin/fibrinogen binding protein of *S. suis*.

Applicant submits that in view of the foregoing, the Specification more than adequately describes the isolated or recombinant nucleotide sequence as presently claimed. Applicant additionally submits that such disclosure would be readily apparent to one of ordinary skill, as the disclosure, in part, is based on the common principles of nucleic acid hybridization. Accordingly, applicant respectfully requests withdrawal of the 35 U.S.C § 112, first paragraph, new matter rejection.

CONCLUSION

In light of the above amendments and remarks, applicant respectfully requests reconsideration of the application. If questions remain after consideration of the foregoing, or if the Office should determine that there are additional issues which might be resolved by a telephone conference, the Office is kindly requested to contact applicant's attorney at the address or telephone number given herein.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Todd E. North', with a stylized, cursive script.

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Date: September 18, 2008
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